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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Minoru Furuichi

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08/25/2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

JACOBSON, MICHELE LYNN

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

08/25/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/820,878	<b>Applicant(s)</b> FURUICHI ET AL.	
	<b>Examiner</b> MICHELE JACOBSON	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/1/08 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 9-14, 18-20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. U.S. Patent No. 7,011,872 (hereafter referred to as Ding).

4. Ding teaches a blend of 1,2 syndiotactic polybutadiene with a crystallinity of less than 50% and most preferably within the range of about 13% to about 40% for use in fabricating medical products such as tubings, pump compatible tubings (Col. 8, line 44), peritoneal dialysis administration sets (Fig. 4), I.V. administration sets (Fig. 5), drip chambers (Fig. 6) and the like. (Col. 3, lines 50-51, 61-66, Col. 8, lines 58-60) Bonding

together tubes made with the 1,2 syndiotactic polybutadiene polymer blends and rigid connector components including an example of bonding a polybutadiene blend tube to a polybutadiene blend drip chamber is recited. (Col. 9, lines 41-47) The polymer blends and products (such as tubes) made therefrom are disclosed to be exposed to sterilization doses of electron beam radiation in the range from about 15 kGys to about 45 kGys. (Col. 5 line 65-Col. 6 line 2, Claim 22) Exposing the blend or product to radiation within this range is recited to cause a measurable change in the gel content of the blend or product which may increase the mechanical strength and prolong the time of service in a medical pump tubing application. (Col. 6, lines 9-18) A tubing made from the inventive composition of Ding is recited to be bonded to a rigid component such as a connector. (Col. 9, lines 28-30) An example of joining a polybutadiene tubing to a polybutadiene drip chamber both made of the polybutadiene compound of the invention is recited. (Col. 9, lines 44-47)

5. It is well known in the polymer art that varying the crystallinity of a polymer will predictably change the rigidity of the resulting polymer composition. Ding recites that the tubing comprising the 1,2 syndiotactic polybutadiene of the invention can be solvent bonded to a more rigid component (i.e. a drip chamber) comprised of the same material.

6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have produced a tubing with crystallinity in the lower region of the range recited by Ding and a rigid connector such as a drip chamber in the higher region of crystallinity recited by Ding in order to obtain the a flexible tubing as recited by Ding that could be attached to a connector with greater rigidity as recited by Ding. The

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application of well known teachings in the polymer art to Ding would have produced a tube with lower crystallinity than the drip chamber it was attached to. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the crystallinity of these components within the ranges recited by Ding. In the absence of any showing of criticality of the ranges recited or unexpected results the crystallinities recited by applicant would have been obvious to one of ordinary skill in the art to optimize in order to vary the rigidity of the structure produced. Such an optimization of the crystallinity of the tube to produce a predictably flexible product and the crystallinity of the connector to produce a predictably rigid component would have produced the invention as claimed in claims 1-4, 9-14, 18-20 and 23-25.

7. Regarding claims 1-4 and 23: The medical tubing with a crystallinity of about 5-25% solvent bonded to a drip chamber (i.e. connector) with a crystallinity of about 26-40% as claimed 1-4 and 23 would have been the result of the optimization of Ding as recited above. Such an invention would obviously be used in a medical instrument such as an I.V. administration set recited by Ding which is the same as the invention claimed in claim 23.

8. Regarding claims 24 and 25: Depending on the amount of rigidity desired for the application of the 1, 2 syndiotactic polybutadiene article it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected any crystallinity within the range recited by Ding. This selection of crystallinities would have produced the invention as claimed in claims 24-25.

9. Regarding claims 12-14: Ding explicitly teaches cross-linking of the medical tube by electron beam radiation as recited in claims 12-14.

10. Regarding claims 9-11 and 18-20: Since the polymer blends, crystallinity and article treatments recited by Ding are the same as those recited by applicant, the medical member and connector of Ding would be expected to inherently exhibit the properties as claimed by applicant in claims 9-11 and 18-20. See MPEP 2112 V. Ding recites exposure to e-beam radiation, which results in cross-linking of the polymer increasing its melting point and making it inherently able to withstand steam sterilization. (Claims 9-11) Since Ding recites the same polymer blend as applicant, the amount of halogen would inherently be within the range cited in claims 18-20.

11. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. U.S. Patent No. 7,011,872 as applied to claims 1 and 12-14 above in view of Doheny Jr. U.S. Patent No. 5,063,005 (hereafter referred to as Doheny)

12. Ding does not explicitly state the energy of the electron beam so that a product of the electron beam and dose may be calculated. The range of electron dose recited by Ding (less than 5 Mrad) falls within that recited by the applicant in the specification (1-100 Mrad).

13. Doheny, Jr. teaches electron beam irradiation of polyolefins to obtain a desired modulus. Doheny, Jr. teaches that needed radiation can be readily calculated by a skilled practitioner based upon dosage to effect the required cross-linking, such as line

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speed, kilovolts required to provide a penetrating potential and current (column 10, line 44, to column 11, line 2)

14. The motivation to combine Ding with Doheny would have been as Ding recites to provide cross-linking to “increase the mechanical strength and prolong the time of services in a medical pump tubing application”. (Col. 6, lines 16-18)

15. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Ding with Doheny in order to produce a medical tubing and connector made by electron beam dosing within the range disclosed by applicant. Since Ding discloses cross-linking of syndiotactic 1,2 polybutadiene from radiation exposure and the benefits it provides, it would have been obvious to and within the ability of one of ordinary skill to optimize the parameters disclosed by Doheny (such as dosage and energy) to obtain the invention as claimed in claims 15-17.

16. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. U.S. Patent No. 7,011,872 as applied to claims 1 and 2 above in view of Bacehowski et al. U.S. Patent No. 4,299,256 (hereafter referred to as Bacehowski).

17. Ding is silent regarding the addition of lubricant to the polymer blends used to make the medical tubing and connector of the invention.

18. Bacehowski teaches adding from 1 to 5 parts by weight of silicone oil to the polymer blend of a tubing for use as roller pump tubing. (Col. 2, lines 8-10)

19. The motivation to combine Ding with Bacehowski would have been as Bacehowski recites to provide a permanently lubricated tubing surface “even when

some of the surface is worn away by continued abrasion or friction, so that the tubing can have a greatly extended life under such conditions of abrasion or friction". (Col. 1, lines 23)

20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Ding with Bacehowski in order to produce a syndiotactic 1,2 polybutadiene medical tubing with 10 parts or less of lubricant disposed therein as claimed in claim 21 and 22.

### ***Response to Arguments***

21. Applicant's arguments filed 1/22/08 have been fully considered but they are not persuasive. Applicant asserts on page 7 of the remarks that an important feature of the present invention is that the "crystallinity of the tube is lower than the crystallinity of the connector, so that the tube maintains flexibility after irradiation with an electron beam. In contrast, the crystallinity of the connector is higher than that of the tube, because the connector must have rigidity after irradiation." However, the claims in the instant application do not require that the connector be irradiated. Additionally, were these claims to require that the connector be irradiated, a component that is rigid, would only become more rigid after irradiation. Additionally, it is well known in the medical art that tubing for applications such as I.V. administration sets recited by Ding must be flexible. The tubing recited by Ding is recited to be irradiated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected a



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crystallinity for the tubing recited by Ding that was low enough for the tube to remain flexible after irradiation since flexibility is required for the medical applications recited by Ding.

22. Applicant further asserts on page 7 of the remarks that by using two different types of syndiotactic 1,2 -polybutadiene for the tube and the connector it is easy to join the two components together. Applicant gives no explanation as to why it would be easy to join the two components together nor does this argument dispute the recitation in Ding of a flexible tube and a rigid connector which made of the same materials which would obviously have different crystallinities within the ranges recited by Ding.

23. Applicant argues on page 7 of the remarks that Ding does not recite using separate crystallinity values for the tubing and connector as claimed in claim 1. Although Ding does not explicitly disclose a tube and a connector with the specific crystallinities claimed by applicant it is the examiner's opinion that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the crystallinities recited in Ding in order to produce a flexible tubing a rigid connector as recited by Ding. Applicant asserts that Ding does not disclose a connector with polybutadiene listed as one of the components, but as explained above, the examiner is interpreting the drip chamber comprising 1,2-polybutadiene disclosed by Ding to be equivalent to a connector.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE JACOBSON whose telephone number is (571)272-8905. The examiner can normally be reached on Monday-Thursday 8:30 AM-7 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele L. Jacobson                    /M. J./  
Examiner, Art Unit  
1794

/Carol Chaney/  
Supervisory Patent Examiner, Art Unit 1794